

10/587138

AP20 Rec'd PCT/PTO 21 JUL 2006

"Express Mail" mailing label number EV 393133915 US

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QUEEN THOMAS  
Printed Name

Queen Thomas  
Signature

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Applicant: KHARITONENKOV Alexei

For: USE OF FGF-21 AND A THIAZOLIDINEDIONE FOR TREATING  
TYPE 2 DIABETES

Docket No.: X16455

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

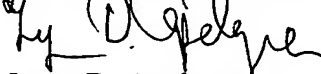
Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) [and provide(s) a copy of each of the listed documents] for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

Applicants request consideration of this information.

Respectfully submitted,



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Eli Lilly and Company  
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P.O. Box 6288  
Indianapolis, Indiana 46206-6288

July 21, 2006

FORM PTO 1449 (modified)  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X-16455	Serial No. <b>107587138</b>
	First Applicant Kharitononkov, A., et al.	
	US Nat'l Entry (if applicable)	Group Art Unit

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Pages or Relevant Figures Appear
	AA	US 6,046,202	04-04-2000	Antonucci, <i>et al.</i>	
	AB	US 6,329,403	12-11-2001	Odaka Hiroyuki, <i>et al.</i>	
	AC				

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	BA	WO 03/11213	02-13-2003	Eli Lilly and Company		
	BB	WO 01/36640	05-25-2001	Chiron Corporation		
	BC	WO 01/18172	03-15-2001	Amgen, Inc.		
	BD	WO 05/61712	07-05-2005	Eli Lilly and Company		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
	CA	AMOS, et al., "The Rising Global Burden of Diabetes and Its Complications: Estimates and Projections to the Year 2010", <i>Diabetic Med.</i> , 14; Suppl. 5; S1-85 (1997)	
	CB	SCHEEN, et al., "Troglitazone: Antihyperglycemic Activity and Potential Role in the Treatment of Type 2 Diabetes", <i>Diabetes Care</i> , 22(9):1568-1577 (1999)	
	CC	OAKES, et al., "The Insulin Sensitizer, BRL 49653, Reduces Systemic Fatty Acid Supply and Utilization and Tissue Lipid Availability in the Rat", <i>Metabolism</i> ; 46:935-942 (1997)	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. Burden Hours Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

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	US Nat'l Entry (if applicable)	Group Art Unit

CD	YOUNG, et al., "Repeat Treatment of Obese Mice with BRL 49653, a New Potent Insulin Sensitizer, Enhances Insulin Action in White Adipocytes. Association with Increased Insulin Binding and Cell-Surface GLUT4 as Measured by Photoaffinity Labeling", <i>Diabetes</i> , 44:1087-1092 (1995)	
CE	OAKES, et al., "A New Antidiabetic Agent, BRL 49653, Reduces Lipid Availability and Improves Insulin Action and Glucoregulation in the Rat", <i>Diabetes</i> , 43:1203-1210 (1994)	
CF	SMITH, et al., "Rosiglitazone Prevents the Onset of Hyperglycaemia and Proteinuria in the Zucker Diabetic Fatty Rat", <i>Diabetes Obesity and Metabolism</i> , 2(6):363-372 (2000)	
CG	BAIRD, et al., "The Fibroblast Growth Factor Family", <i>Cancer Cells</i> , 3:239-243 (1991)	
CH	McKEEHAN, et al., "The Heparan Sulfate Fibroblast Growth Factor Family: Diversity of Structure and Function", <i>Progress in Nucleic Acid Research and Molecular Biology</i> , 59:135-176 (1998)	
CI	REUSS, et al., "Fibroblast Growth Factors and Their Receptors in the Central Nervous System", <i>Cell Tissue Research</i> , 313:139-157 (2003)	
CJ	NISHIMURA, et al., "Identification of a Novel FGF, FGF-21, Preferentially Expressed in the Liver", <i>Biochimica et Biophysica Acta</i> , 1492:203-206 (2000)	
CK	ARONOFF, et al., "Pioglitazone Hydrochloride Monotherapy Improves Glycemic Control in the Treatment of Patients with Type 2 Diabetes: A 6-Month Randomized Placebo-Controlled Dose-Response Study. The Pioglitazone 001 Study Group", <i>Diabetes Care</i> , 23:1605-1611 (2000)	
CL	LEBOVITZ, et al., "Rosiglitazone Monotherapy is Effective in Patients with Type 2 Diabetes", <i>J Clin Endocrinol Metab</i> , 86: 280-288 (2001)	
CM	PHILLIPS, et al., "Once- and Twice-Daily Dosing with Rosiglitazone Improves Glycemic Control in Patients with Type 2 Diabetes", <i>Diabetes Care</i> , 24:308-315 (2001)	
CN	DAY, "Thiazolidinediones: a New Class of Antidiabetic Drugs", <i>Diabetic Medicine</i> , 16: 179-192 (1999)	
CO	OGIHARA, et al., "Enhancement of Insulin Sensitivity by Troglitazone Lowers Blood Pressure in Diabetic Hypertensives", <i>American Journal of Hypertension</i> , 8: 316-320 (1995)	
CP	GOTTSCHLING-ZELLER, et al., "Troglitazone Reduces Plasminogen Activator Inhibitor-1 Expression and Secretion in Cultured Human Adipocytes", <i>Diabetologia</i> , 43:377-383 (2000)	
CQ	MOLLER, "New Drug Targets for Type 2 Diabetes and the Metabolic Syndrome", <i>Nature</i> , 414:821-827 (2001)	

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	CR	DEUTSCHER, "Maintaining Protein Stability", <i>Methods in Enzymology</i> , 183:83-89 (1990)	
	CS	HAUNER, "The Mode of Action of Thiazolidinediones", <i>Diabetes/Metabolism Research and Reviews</i> , 18:S10-S15 (2002)	
	CT	SHARMA, et al., "Diabetic Kidney Disease in the db/db Mouse", <i>American Journal of Physiology. Renal Physiology</i> , 284(6):F1138-1344 (2003)	
	CU		
	CV		
	CW		
	CX		

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